



# UNITED STATES PATENT AND TRADEMARK OFFICE

*m/*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/596,221	07/15/1996	THOMAS A. SILVESTRINI	251692002120	5679

7590

12/08/2003

McCutchen Doyle Brown & Enerson LLP  
Three Embarcadero Center  
Suite 1800  
San Francisco, CA 94111-4067

EXAMINER
----------

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
----------	--------------

3738

//

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/596,221

Applicant(s)

SILVESTRI

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on November 6, 2003, and September 15, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23,24,28,30-37 and 40-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,24,28,30-37 and 40-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 3738

The disclosure is objected to because of the following informalities: In claim 28, line 4, -a-- should be inserted after "of", last occurrence. In claim 41, line 1, "is" should be replaced by --are--. Appropriate correction is required.

Claims 23, 24, 40, 41, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 23, line 4, the term "construed" is inappropriate and confusing and should apparently be replaced by --constructed--. In claim 40, "said section" is indefinite because more than one section is set forth in claim 23. Claim 44 is indefinite and confusing for similar reasons.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, 28, 30-37, and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Silvestrini et al., US 5,300,118. Particular attention is directed to Figures 11A and

Art Unit: 3738

11B; column 2, lines 13-15; column 3, lines 60-68; column 6, lines 47-50 and 58-60; and column 10, lines 14-27 and 38-42. Regarding newly added claim 44, the sections are removable after implantation in the sense that the entire device is *capable* of being removed after implantation.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Civerchia et al., WO 88/02622. The embodiments illustrated in Figures 14, 16, and 17 include axially contiguous sections each capable of being implanted within a human cornea (page 27, lines 1-5), the optical section having different cross-sections from that of the tab sections. All three sections are formed of a collagen-hydrogel (page 25, lines 25-28; page 26, lines 12-13 and 21-23), and such a material having an elastic modulus less than 500 psi would have been obvious, if not inherent, from the fact that the material involves a high water content cross-linked hydrogel in the presence of anchoring macromolecules (page 1, lines 10-12; page 3, lines 1-2; page 5, lines 8 and 24-27; page 6, line 4; page 11, lines 12-13; page 27, lines 16-18; etc.). Alternatively, to include tab sections as taught by Civerchia et al. on the soft, high water content hydrogel structures of the prior art discussed in Civerchia et al. would have been an obvious step backward in order to compare epithelial cell growth and anchorage properties between the prior art and the Civerchia et al. improvement (which adds collagen macromolecules).

Art Unit: 3738

The Applicant's remarks have been reviewed. As pointed out in the Advisory Action mailed on September 29, 2003, a "step function" is a function "which makes an instantaneous change in value from one constant value to another" (*The Wordsworth Dictionary of Science & Technology*, Wordsworth Editions Ltd., Hertfordshire, 1995). The instantaneous changes can be increases or decreases or both. The device as set forth in present claim 23 and others need only have *two* adjoining sections, with the cross sectional area of the implant changing substantially stepwise from one section to the other. Said Advisory Action further refers to column 10, lines 21-24, of Silvestrini, which states that the device can have "a plurality of notches of *different heights*" (emphasis added) so that there are several steps with various instantaneous changes, both increasing and decreasing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Dave Willse  
Primary Examiner  
Art Unit 3738